APPENDIX C

APPLICATION OF CONNELL ET AL

FILED APRIL 19, 1991

# System 1000 Development

## Architecture

### General Description

#### Main Controller Hardware (Host)

The System 1000 machine is controlled by an 80XX microprocessor (uP) and three 8040 microcontrollers (uC). The 80XX uP is located on an IBM PC/AT compatible motherboard, with its primary responsibilities being:

- User interface (CRT display and touch screen)
- State machine control (Rinse, Prime, Dialyze,...)
- Microcontroller communications
- Conducting self tests
- Calibrations

The firmware for the 80XX uP is located on the Memory Board, which plugs into the motherboard. The Memory Board can hold up to 384K of ROM (read only memory). In addition it also contains 8K of nonvolatile static RAM (random access memory) (for calibrations and machine parameters), a memory card interface, an RS-232 interface, and a time of day clock. The 80XX uP has access to 256K of dynamic RAM located on the motherboard.

The 80XX uP controls the operation of the machine through its connection to the following additional boards which are plugged into the motherboard:

- EGA display board
- Touch screen interface board
- Blood Pump system controller board
- UF/Proportioning system controller board
- I/O system controller board
- RS-232 board (optional for patient blood pressure monitor)

#### Main Controller Software (Host)

The host control program is written in the 'C' programming language. The program source code is compiled, linked and loaded into programmable read only memory. This memory resides on the embedded hardware system memory board.

The purpose of the host control program is to:

- Gather data from the Input/Output, Blood Pump and Ultrafiltration controller sub-systems, and output control functions to the various controller sub-systems.
- Input data from user interface touch screen.
- Monitor the data for violation of alarm limits and unsafe operating conditions, and to set the appropriate program alarm condition indicators;

- Evaluate the data to determine the current operating state of th control program, i.e. Standby, Rinse, Self Test, Prime and Dialyze.
- Update the display data to the CRT porti n of the user interface.

## Blood Pump Control System

Five subsystems are controlled or monitored by the blood pump controller. They are:

- Blood pump
- Blood pressure measurement (arterial, venous and expansion chamber)
- Heparin delivery
- Level adjust
- Ambient temperature

### Blood Pump Controller

The purpose of the blood pump controller is to supply power to the blood pump motor such that the pump head will turn and pump at a rate selected by the operator.

The blood pump controller system consists of the following major components:

| *Description* | *Location* |
|---|---|
| User parameter entry | Host controller |
| Software Speed Error Control | Bld Pmp Controller |
| Hardware Speed Error Control | BP Power Board |
| Optical speed sensor | On motor shaft |
| Motor Power Driver Circuitry | BP Power Board |

The operator enters the desired blood pump rate information on the video screen (CRT) touch panel. The host controller (80XX microprocessor) converts this information to the appropriate motor rate which it then sends to the Blood Pump controller (8040) on the Blood Pump Controller board. The 8040 controller converts the motor rate information to an analog level, which is fed to a motor speed control IC (LM2917-8) on the Blood Pump Power board.

An optical speed sensor is mounted on the rear shaft of the blood pump motor, with an LED being positioned on one side of the shaft, and a photo transistor on the opposite side. The shaft has two holes drilled through it, with each hole being perpendicular to the shaft and to each other. This results in four optical pulses received per shaft revolution.

This tachometer signal is monitored by both the LM2917-8 and the 8040 controller. The LM2917-8 provides quick responding speed control by comparing the motor speed with the desired speed information from the 8040. The result of this comparison is an error signal which provides an input to the motor power driver circuit.

The motor power driver provides a +24 V pulse width modulated drive to the motor at a frequency of approximately 30 KHz. This drive

is current limit protected, to prevent damage in th vent of a stalled m tor.

The 8040 compares the tachometer motor speed information with the desired speed commanded by the 80XX and corrects the level provided to the LM2917-8 accordingly. In this way the 8040 guarantees the ultimate accuracy of the pump, with the LM2917-8 circuit not requiring any calibration. In addition, the 8040 can monitor for control problems, such as under speed or over speed, which may result from failures in the LM2917-8 or motor drive circuitry.

The 8040 also monitors the motor speed independent of the tachometer signal using the motor's back EMF. Periodically (every 0.5 second) the motor drive is turned off for approximately 6 millisecond and the voltage at the motor terminals is measured. Though this does not result in as precise an indication as the tachometer signal, gross failures can be determined, such as when the tachometer signal is lost.

**Blood Pressure Measurement**

The blood pressure measurements include the venous, arterial and expansion chamber (for Single Needle treatment) pressures. All three measurement systems include identical hardware. Each pressure is sensed by a SenSym SCX15 gauge sensing pressure transducer mounted to the Blood Pump Power board. Each transducer is connected to a differential amplifier designed to provide a measurement range from –400 to +600 mmHg. The output of each amplifier drives an A/D input channel of the Blood Pump Control system, at which point it is converted to a 10 bit digital value. The calibration of the each pressure input is handled entirely in software, requiring that the design of each amplifier guarantee that its output remain within the A/D input range of 0 to +5 V over the input pressure range and over all component tolerances.

**Heparin Delivery**

Heparin delivery is accomplished by stepping a stepper motor which rotates the pinion of a rack and pinion mechanism. The pinion moves the rack, and the mechanical fixture is such that the plunger of th heparin syringe moves the same distance. The stepper motor is controlled by the 8040 microcontroller located on the Blood Pump Controller board. When the operator enters a desired heparin rate in milliliters per hour (mL/h) via the front panel touch screen, the host 80XX microprocessor converts this information to the appropriate motor step rate and passes it to the Blood Pump microcontroller. The Blood Pump microcontroller outputs a motor step rate logic signal to the Blood Pump Power board where the heparin motor power drive circuitry energizes the appropriate stepper motor coil.

The motor step rate logic signal from the Blood Pump microcontroller is also input to the IO Controller board 8040 microcontroller. The IO microcontroller monitors this signal to determine if the heparin motor is going the appropriate speed. If it determines that an overspeed condition exists, it disables the heparin motor via a disable line that goes to the Blood Pump Power board.

There are two optical sensors to provide inf rmation about the state of the heparin pump. The disengage sensor detects wh n the front panel syringe holder arm is in the disengage position. The end-of-stroke sensor detects when the pinion is raised up n the rack, which occurs when the gear teeth are not meshed. This is an indication of an overpressure condition. The Blood Pump microcontroller monitors the state of these sensors and passes the information to the host 80XX microprocessor.

### Level Adjust

The level adjust system allows the operator to change the blood level in the arterial and venous drip chambers. A level up and level down button exists for each drip chamber. The 8040 microcontroller on the Blood Pump Controller board monitors the button positions. When a button is pressed, a valve selects that drip chamber and power is supplied to the motor such that the pump head of a peristaltic pump rotates to apply a positive or negative pressure to the drip chamber. The software logic only accepts one button press at a time. If two buttons are pressed simultaneously, both are ignored.

The motor drive circuitry is located on the Blood Pump Power Board. The motor may be driven in the forward or reverse direction. A direction signal from the Blood Pump Controller Board, along with a pulse width modulated motor rate signal controls two bipolar half bridge motor drivers. Both half bridge motor drivers receive the same motor rate signal, while the motor direction signal is high at one and low at the other to determine the direction the motor runs. The half bridge drivers provide a 24 V pulse width modulated drive voltage of approximately 30 KHz to the motor.

### Ambient Tempertature Control

The purpose of the cabinet cooling system is to keep the internal temperature of the cabinet lower than the 50°C maximum temperature at which that the electronic components are guaranteed to operate. (Most electronic components are rated to operate at 60°C, the exception is the solid state relay used for heater control.) A fan is located at the base of the cabinet and exhausts the warm cabinet air. An intake vent for the ambient room temperature is located below the CRT on the back of the machine.

The cabinet cooling system consists of the following major components:

| *Description* | *Location* |
|---|---|
| Cabinet Fan | Base of cabinet |
| Blood Pump Temperature IC | Blood Pump Power Bd |
| Misc IO Temperature IC | Misc IO Electronics Power Bd |
| Software Fan Control | Host controller |
| Cabinet Fan Drive | Blood Pump Power Bd |

The two LM35DZ temperature ICs are located on the Blood Pump and Misc IO Electronics power boards. This IC outputs a voltage linear with temperature in °C (10.0 mV/°C). These temperature readings are input to the fan control software.

The fan control software always responds to the higher of the two temperatures. Typical values are as follows. At 46°C the fan turns on in the low speed mode and at 48°C it turns on in the high speed mode. There is a 2°C of hysteresis at these thresh ld temperatures, i.e. the fan returns to low speed at 46°C and turns off at 44°C. In addition, at 60°C a cabinet temperature alarm occurs that results in the machine shutdown state.

The fan power driver is located on the Blood Pump Power board. A motor rate signal from the Blood Pump Controller board determines the duty cycle of a 30 KHz pulse width modulated signal. This signal is input into a passive filter to provide a DC signal to the motor.

## UF/Proportioning Control System

The UF/Proportioning Control system monitors and controls the System 1000 dialysate preparation. Six subsystems are controlled or monitored by the UF/Proportioning system. They are:

a. Temperature Control

b. Proportioning Control

c. Flow Control

d. UF Removal Control

e. Conductivity Monitoring

f. Temperature Monitoring

### Temperature Control

The UF/PROP system controls the dialysate temperature by enabling a zero voltage crossing solid state relay, which provides the power to a 1500 W heater, with a 5 Hz pulse width modulated digital signal (heater enable signal). The duty cycle of the heater enable signal is updated every 0.5 seconds with the sum of the past duty cycle and a temperature error correction value. The correction value is proportional to the difference between the desired temperature (stored by the host) and the measured control temperature (measured immediately down stream of the heater housing).

The host determined desired temperature is calculated using the user entered desired temperature and the stable "B" conductivity probe temperature. If the stable "B" conductivity probe temperature is different from the user entered desired temperature by more than 0.05°C, then the control temperature threshold sent to the UF/PROP controller is updated so that the "B" conductivity probe temperature will equal the user entered desired temperature. In this way, the dialysate temperature at the "B" conductivity probe will be adjusted so that flow rate and ambient temperature effects on the "B" conductivity probe temperature (and the primary temperature, displayed on the video screen) will be compensated. This control temperature adjustment is performed a maximum of every 5 minutes.

### Proportioning Control

The UF/PROP system controls the concentrate(s) to water proportioning ratios by controlling the dialysate flow rate, the "A" concentrate flow rate, and the "B" concentrate flow rate.

The "A" and "B" concentrate pumps are stepper motor driven (each by a cam/follower) diaphragm pumps which deliver a calibrated volume of concentrate per stepper motor r volution. Their flow rates are controlled by controlling the speed of the stepper motors. The concentrate pumps are unidirectional and utilize the proper actuation of a three-way valve for their intake and output pumping strokes. The intake stroke is synchronized by a signal that is generated by an optical interrupter sensor which senses a pin mounted on the cam of the pump assembly.

The UF/PROP controller utilizes the fact that the stepper motors require 200 motor steps per revolution (between each synchronization pulse) to check the concentrate pumps for stepping errors. If late or early synchronization pulses are received then the associated error conditions are reported on the screen during the Technician Mode of the machine.

During the Rinse Mode, the host determines the concentrate treatment mode based on the "A" and "B" rinse port interlock information. If the "B" concentrate line is not on the "B" rinse port, a bicarbonate treatment is initiated by setting the proportioning ratios and the conductivity alarm limits appropriately. Conversely, if the "B" concentrate line is in the "B" rinse port, an acetate treatment is initiated. Using the dialysate flow rate and the proportioning ratios, the host determines the associated concentrate flow rates and stores the two concentrate pump speeds in the UF/PROP controller. The porportioning mode (for acetate or bicarbonate dialysis) cannot b changed in the Prime or Dialyze Modes.

The control of the dialysate flow rate is described in the Flow Control section of the UF/PROP controller description.

**Flow Control**

The UF/PROP system controls the dialysate flow rate by controlling the time between the switching of the flow equalizer (volumetric pump) valves (provided that all the fluid within the flow equalizer chambers has been exchanged).

The average flow equalizer volume is calibrated (measured) during the Calibration Mode. The time between the switching of the flow equalizer valves is scaled by the host (according to the calibration constant) and stored in the UF/PROP controller so that the user entered desired dialysate flow rate is achieved.

To guarantee the complete fluid transfer to/from the flow equalizer chambers two flow sensors are located within the fluid path to detect the absence of dialysate flow. The time at which both sensors detect no flow has been defined as end-of-stroke. The end-of-stroke time has been defined as the time between moment end-of-stroke was sensed and the desired flow equalizer valve switch time. Since the supply pump speed controls the instantaneous dialysate flow rate, the UF/PROP controller servos the supply pump speed in order to maintain a consistent end-of-stroke time.

Since the flow equalizer volume is calibrated and the end-of-stroke time is controlled, the UF/PROP system can accurately control the dialysate flow rate to the user entered value.

## UF Removal Control

The UF/PROP system controls the UF removal rate by controlling the time between the switching of the UF r moval metering device valves. The UF/PROP system controls the accumulated UF volume by counting the number of UF rem val meter strokes.

Since the UF removal metering device volume is calibrated (measured) in the Calibration Mode, the rate which the host (80XX microprocessor) passes to the UF/PROP controller (number of seconds between valve switches) is scaled so that the user entered UF removal rate is achieved.

In the same way, the user entered UF removal volume is scaled by the UF metering device's stroke volume to a number of UF meter strokes. The host passes the number of UF meter strokes to the UF/PROP controller. The UF/PROP controller will then switch the UF removal meter valves and decrement the stroke number, at the desired rate, as long as the stroke number is greater than zero. The host can then calculate the UF removal volume accumulated by subtracting the number of UF strokes remaining, scaled by the stroke volume, from the operator entered desired UF removal volume. The accumulated volume is displayed during the Dialyze Mode. This value remains during the Rinse Mode and is cle_red upon the entry of the Self Test Mode.

In Rinse, the UF removal rate is 3.6 L/h and screen indicates no UF volume accumulated. During the Self Test Mode, no UF removal occurs except for during specific self tests performed by the machine (no UF volume is accumulated). In the Prime Mode, the UF removal rate is set by the operator and is no greater than 0.5 L/h (no UF volume is accumulated). During the Dialyze Mode, the UF removal rate is set by the operator and is limited to be between 0.1 and 4.00 L/h. For UF removal to occur in the Dialyze Mode the following conditions must be met:

1. A target UF volume and a UF rate have been entered (or treatment time and target UF volume have been entered and a machine calculated UF rate is used).
2. The blood pump is pumping.
3. The target UF volume has not been reached.

## Conductivity Monitoring

Conductivity is used as a measurement of the electrolyte composition of the dialysate. Conductivity is usually defined as the ability of a solution to pass electrical current. The conductivity of dialysate will vary due to the temperature and the electrolyte composition of the dialysate.

The UF/PROP system measures conductivity at two locations in the flow path using alternating current resistance measurements between each of the conductivity probes' electrode pairs. The two flow path locations are at the "A" conductivity probe and the "B" conductivity probe, which are located immediately down stream of the "A" and "B" mixpoints/ mixchambers, respectively.

One electrode of each of the probes is stimulated with a 1 kHz ac v ltage while the other is held at virtual ground (current sense electrode). Two voltages are produced by the resistance measurement circuit. The ratio of the voltages is proportional to the resistance of the respective probe. The resistance of the probes has been modeled as a function of temperature and conductivity. Since each of the conductivity probes contains a thermistor, the temperature at each of the probes is known. Using the model that was derived for the probes, the temperature measured at the probes, and the resistance measured at the probes the conductivity is calculated.

Each conductivity probe is calibrated during the Calibration Mode, at which time the resistance of each probe is measured at a known conductivity and temperature (by the use of an external reference meter) for the scaling of the probe's base resistance in the relationship described previously.

The UF/PROP system generates alarms from the measured conductivities at the "A" and "B" probes. Since these conductivity alarms are used to verify the proportioning ratios, the alarms are generated by testing the "A" conductivity and the "B" portion of the total conductivity ("B" portion = "B" conductivity – "A conductivity). The alarm limits are determined from the concentrate treatment mode and are stored in the UF/PROP controller by the host. Therefore only during a bicarb treatment would the host store a non-zero expected "B" conductivity portion.

The host determines the concentrate treatment mode during the Rinse Mode by reading the "A" and "B" rinse port interlock information. If the "B" concentrate line is not on the "B" rinse port, a bicarbonate treatment is initiated by setting the proportioning ratios and the conductivity alarm limits appropriately. Conversely, if the "B" concentrate line is in the "B" rinse port, an acetate treatment is initiated. Upon exiting the Rinse Mode the concentrate treatment mode is set for the remainder of the dialysis treatment (concentrate treatment mode is only adjusted in the Rinse Mode).

## Temperature Monitoring

The UF/PROP system measures the dialysate temperature at three locations in the fluid path. The first location is directly after the heater and this thermistor, the heater thermistor, is used for the primary temperature control feedback. The next two thermistors are contained in the "A" and "B" conductivity probes. These temperatures are used to temperature compensate the "A" and "B" conductivity measurements. The "B" conductivity temperature is also used to generate a backup high temperature alarm.

The temperature measurement circuit used throughout the machine consists of a voltage divider with a Thevenin Equivalent circuit of 3062 Ω in series with a 7.55 V supply. The voltage divider circuit when connected to the thermistor used in the temperature measurement system referenced to ground produces the voltage to temperature relationship of

$$T\,(°C) = (3.77V - Vtemp) * 12.73\,(°C/V) + 37°C.$$

The tolerance on the component parameters used in the temperature measurement system can be as great as 10%, therefor the temperature to voltage relationship must be calibrated. Calibration of the temperature measurements is a two point calibration done at 30 and 40°C. The calibration procedure results in a calibration constant for both the slope and the offset for each temperature probe/circuit.

In the UF/PROP controller the voltage described above as Vtemp is measured for the three temperature probes in its system on a scheduled basis (every 0.2 seconds for the "A" and "B" temperatures and every 1 second for the heater temperature).

The temperature that is displayed on the video screen is measured at the primary ("dialysate") conductivity probe, located just before the bypass valve, by the IO controller.

## Miscellaneous Input/Output Control Systems

Nine subsystems are controlled or monitored by the I/O control system. They are:

- Air detector
- Blood leak detector
- Dialysate pressure monitor
- Heparin pump overspeed monitor
- Bypass system and flow sensor
- Conductivity monitor
- Temperature monitor
- Line clamp
- Power fail alarm

### Air Detector

The air detector assembly utilizes a set of 2 MHz piezo crystals. One crystal functions as an ultrasonic transmitter and the second crystal functions as a receiver. The emitter and detector are housed into identical assemblies. There is a distance of 0.20 inch between these assemblies into which the venous blood line is placed during dialysis. The emitter is driven by a 2 MHz squarewave that is derived from a crystal oscillator located on the I/O Electrical Power board. When there is fluid in the blood line between the crystal assemblies, the 2 MHz signal is coupled to the detector assembly. The return signal from the detector assembly is amplified and rectified by two independent circuits also located on the I/O Electrical Power board. These dc output levels are monitored using two different methods. The first method is the software generated alarm and the second is the hardware generated alarm.

#### Software Alarm Detection (Primary Alarm)

One output is fed from the I/O Electrical Power board to an A to D converter and read by the 8040 microcontroller on the I/O Controller board. This value is averaged over a 400 msec time period and reduced by multiplying it by 15/16 and subtracting 50 mV (for noise immunity). This new value is then converted back to an analog level

to be used as an alarm limit. This software generated limit is compared to the rectified dc signal from the detector. The output state of this comparator is monitored by the on-board 8040. When th unaveraged signal falls below the software generated limit for longer than a calibratable time period, an alarm occurs. Sensitivity of the software alarm is 10 microlitres at 300 mL/min blood flow.

**Hardware Alarm Detection (Secondary Alarm)**

The hardware alarm is redundant to the software generated alarm. This alarm uses two comparators on the I/O Electrical Power board. One comparator looks for a minimum dc level from the rectified detector signal which guarantees the presence of fluid in the venous tubing. The second comparator is ac coupled to react to a large air bubble in the tubing. Sensitivity of this detector is approximately 300 microlitres at 300 mL/min blood flow. Both comparator outputs are wire OR'd together so that either comparator will generate an alarm.

**Blood Leak Detector**

The detector assembly consists of a high efficiency green LED and a photocell. These components are installed into a housing through which spent dialysate passes. Both of these components connect to the I/O Hydraulic Power board. The LED is connected to a voltage to current converter on the I/O Hydraulic Power board. The input to this circuitry comes from the I/O Controller board. The photocell is tied to the +5 V reference supply through a 750k ohm resistor. This provides a voltage divider which is monitored on the I/O Controller board.

The current through the LED is adjustable and controlled via a D to A output from the I/O Controller board. The light intensity of the LED is adjusted to illuminate the photocell to a point where its resistance is below the alarm threshold. During a blood leak, the presence of blood in the housing attenuates the light striking the photocell which causes an increase in both the photocell resistance and voltage. The increase in voltage (monitored by the microcontroller on the I/O controller board) results in a blood leak alarm.

**Dialysate Pressure Monitor**

The dialysate pressure is sensed by a resistive bridge pressure transducer located just upstream of the dialyzer. The transducer is connected to a differential amplifier circuit on the IO Hydraulics Power board designed to provide a measurement from –400 to +500 mmHg. The differential amplifier circuit also has an offset input that comes from a software calibratable variable, DAC_OFFSET. The output of the amplifier drives an A/D input channel of the IO Controller system, at which point it is converted to a 10 bit digital value. The calibration of the pressure input is handled entirely in the software, requiring that the design of the amplifier guarantee that the output remains within the A/D input range of 0 to +5 V over the input pressure range and over all component tolerances.

**Heparin Pump Overspeed Monitor**

To insure that the heparin pump does not exceed its set speed, the IO controller board software monitors a clock signal from the Blood Pump Controller board that is equivalent to 1/4th the heparin pump step rate. In the event that a heparin pump overspeed occurs, the IO

controller board disables the heparin pump via a hardware line that goes to the Blood Pump Power board and notifies the host of the alarm.

To determine if the heparin pump is running the correct speed, the time it takes for ten clock signals to occur is measured (and stored in variable HEPTIMER) and compared against a minimum time period that is set by the host (HP_P_MIN). If the measured period is less than the host set limit, a normal speed alarm occurs. The host is notified of the normal speed alarm and the heparin pump is disabled via the hardware line to the Blood Pump Power board.

When the heparin pump rate changes, the host resets the minimum time period, HP_P_MIN, and the IO controller waits for the first clock signal to restart the timer (this first clock is not counted as one of the ten). In this way, the alarm logic is resynchronized with the heparin pump stepper motor.

The IO controller board also monitors the total amount of heparin delivered in the high speed bolus mode. When it receives clock signals at a rate faster than a predetermined speed, it assumes the pump is operating in the high speed mode. It has a high speed counter, H_SPD_CNTR, that is set by the host. If more high speed counts occur than are in the counter, a high speed alarm occurs. The host is notified of the high speed alarm and the heparin pump is disabled via the hardware line to the Blood Pump Power board.

**Bypass System and Flow Sensor**

The bypass mode is initiated when a primary dialysate alarm is detected by the IO Controller board, when a redundant dialysate alarm is detected by the UF/PROP Controller board, when the host requests bypass, or when the manual bypass button is pushed.

The bypass valve is in the bypass position when deenergized. It is driven from the nominal +24 V supply with a straight on/off transistor control on the IO Hydraulics Power board.

To verify that there is not a failure in the bypass system, a flow sensor just downstream of the predialyzer bypass valve checks for flow. If flow exists during the bypass mode, a Bypass Fail Alarm is set and the machine is put in the safe, nonfunctional, Shutdown state. If there is no flow when not in the bypass mode, a No Flow alarm is generated.

This flow sensor consists of two thermistors. The first is a reference thermistor used to determine the fluid temperature. The second thermistor uses thermal dilution to sense the fluid flow. The voltage outputs from the thermistors on the IO Hydraulics Power board drive A/D input channels on the IO Controller board where they are converted to 10 bit digital values. A software algorithm in the IO Controller code uses these inputs to determine the flow condition. The design of the voltage divider guarantees that the output remains within the A/D input range of 0 to +5 V over the input temperature/flow range and over all component tolerances.

**Conductivity M nitoring**

The conductivity probe itself consists of two stainless steel probes inserted into the flowpath just prior to the dialyzer. The drive signal for the conductivity probes is a capacitive coupled squarewave generated on the I/O Hydraulic board. This signal is sent to the conductivity probe and a monitor circuit. Both the monitor circuit and the return signal are rectified and filtered. These dc values are routed to I/O Controller board along with the temperature signal.

On the I/O controller board, the temperature, conductivity, and conductivity reference signals are input to an A to D converter that is monitored by an on board 8040 microcontroller. The microcontroller calculates the temperature compensated conductivity. This value is then displayed on the CRT as the conductivity in milliSiemens.

**Temperature Monitoring**

The thermistor installed in the conductivity probe changes its' resistance in response to changes in temperature. This conductivity probe is located just prior to the bypass valve and is the final temperature and conductivity measurement point. The values for conductivity and temperature measured at this point are displayed on the CRT and are used to generate the primary alarms for patient safety. If either value is outside of set limits, a bypass condition and audio alarm occur.

The thermistor is wired to a resistor divider network on the I/O hydraulic board. The output of this divider network is sent to the Miscellaneous I/O controller board where it is monitored by the on board 8040 microcontroller via an A to D converter network. From this information, the controller calculates the temperature using offset and gain inrmation stored in the host from the calibration. Calibration of the temperature measurement is a two point calibration done at 30 and 40°C.

**Line Clamp**

The line clamp opens with a solenoid and clamps with a spring return. When the solenoid is not energized, the spring pushes the plunger away from the solenoid. This causes the plunger to clamp the blood tubing. When the solenoid is energized, it pulls the plunger in with enough force to overcome the spring force. This unclamps the blood tubing. In the event of a power failure, the solenoid is de-energized causing the blood line to be clamped.

The solenoid is controlled by the line clamp board. On the line clamp board is a pulse width modulated current controller. This circuit applies sufficient current to the line clamp solenoid to pull in the plunger. After pull in, the controller ramps the current down to a level capable of holding the line clamp open. This cut back in current reduces the temperature of the solenoid, resulting in a more reliable device. Also located on the line clamp board, is a quick release circuit which helps dissipate the power stored in the solenoid. The result of this circuitry is a quicker and more repeatable clamp time over the life of the machine.

ENERGY

Control for the line clamp comes from the Miscellaneous I/O controller b ard via the I/O power board. The control signal for clamp

and unclamp is optically coupled on the line clamp board. This provides electrical isolation between the high voltage used to operate the line clamp and the low voltage used for the control signals from the microprocessor.

### Power Fail Alarm

The power fail alarm circuitry is located on the Misc I/O Electrical Power board, and includes a CMOS power state flip flop powered by a 1 Farad (F) capacitor. The flip flop, which can be toggled by either the front panel power button or the 80XX system controller, provides the following functions:

- When power is not supplied to the machine (i.e. when the +5 V supply is off) and when the flip flop is in the on state, then power is supplied from the 1 F capacitor to the audio alarm device. When power is supplied to the machine, the flip flop's output state is read by the 80XX, which provides indication of the intended machine power state. Also, when the flip flop is in the on state, power is supplied to the front panel power switch LED.
- The first function listed above results in the power fail alarm. The alarm occurs either if the machine loses power while it is running, or if the front panel power button is pressed "on" when there is no power supplied to the machine. The alarm can be silenced by toggling the flip flop off through pressing "off" the front panel power button.

## Power System

The System 1000 power system consists of the following primary components:

- Power line circuit breaker/power switch
- Power transformer input fuse
- Power transformer
- Unregulated +24 V power supply
- +5 V, +12 V and –12 V logic power supplies

All current from the power plug passes through the power line circuit breaker, which doubles as a main power switch. Both sides of the power line are broken by the circuit breaker. Two loads are fed from the breaker, the dialysate heater and the power transformer. Because the transformer draws much less power than the heater, a fuse is in series with its primary, which protects the transformer from a shorted secondary winding.

The transformer has three secondaries: a 20 Vac winding which supplies the +24 V supply, a 120 Vac secondary which supplies th logic power supply, and a 20 Vac winding which supplies the isolated voltage to the RS-232 interface. The +24V supply provides power to the machine's motors and solenoids, as well as to a +12V switcher which powers the CRT display. The logic power supply provides power to all the digital and low power analog circuitry.

## Memory Controller Board

The memory controller board is designed to plug into the (IBM XT compatible) motherboard, and provides the following functions:

1. Six 28-pin EPROM sites allowing 384 Kbytes of ROM (read only memory) for program storage.
2. 8K bytes of non-volatile memory (CMOS RAM with self contained battery).
3. Realtime clock module (self contained with battery).
4. Asynchronous serial communications port (requires external isolation buffers, provided on a separate board).
5. External memory card interface (requires separate personality board).
6. 4 position dip switch for machine configuration control.

This board is designed to operate in conjunction with a modified motherboard. The modification involves disabling the motherboard's data buffers above address 256K. The memory controller's ROM space is mapped into the address space from 256K to 640K, with the portion between 256K and 312K being mapped also to address range 832K to 888K. The code at this upper address range is configured as a BIOS extension, which results in the ROM being given control by the motherboard's BIOS software following power on initialization. Unlike the standard BIOS extensions, the System 1000 code does not return to the BIOS after being given control.

Additional features:

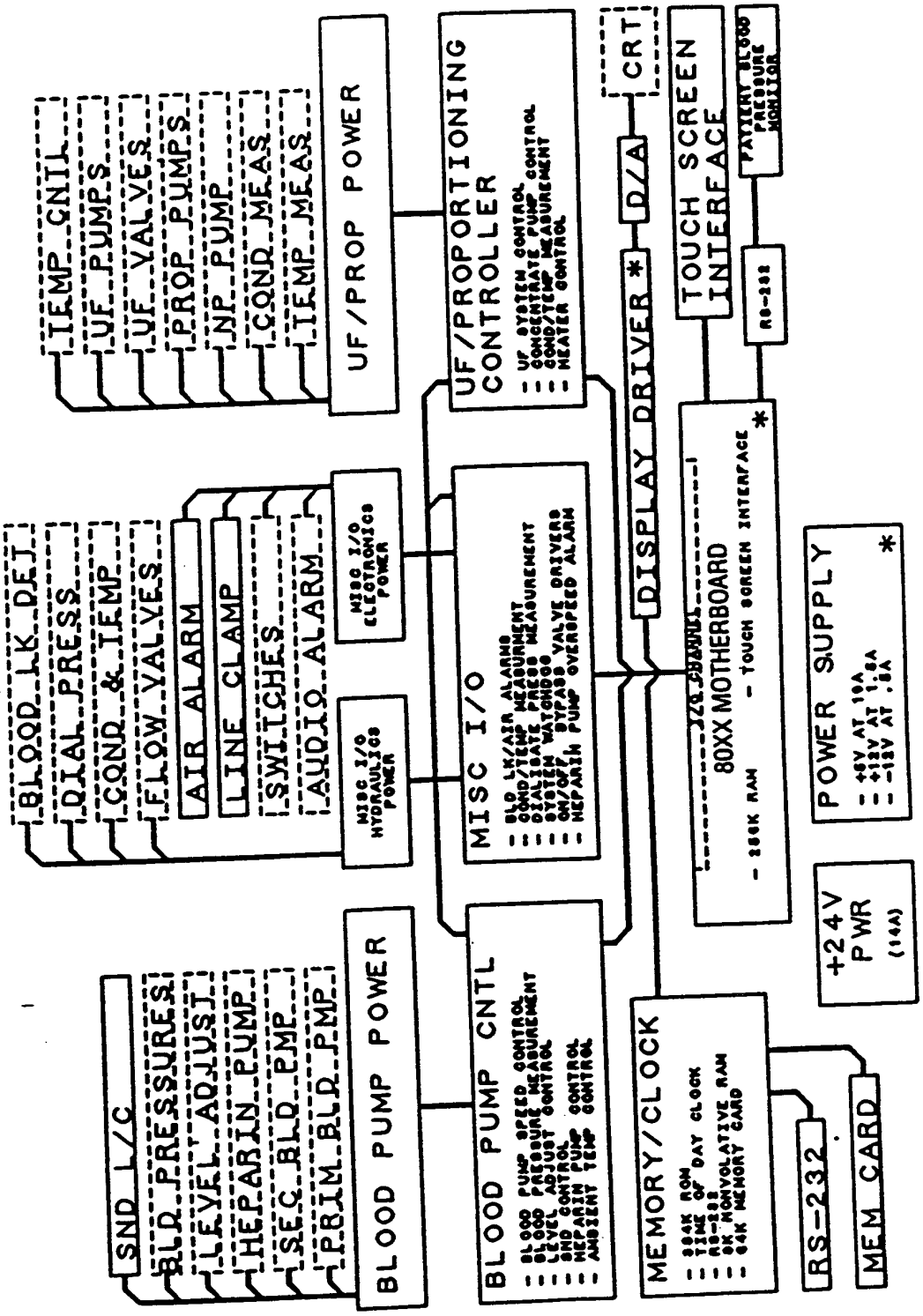
A jumper (JP5) provides the capability of selecting an alternate memory configuration (presently disables ROM chip select functions, allowing operation with a floppy disk and second 256K of RAM) for development purposes. During normal operation, the jumper is either removed or placed on pins 2 and 3.

Circuitry is provided to insert memory wait states for any read or write operation of either memory or I/O (except memory refresh operations on the motherboard RAM array). This compensates for the added buffer delays, as well as the slower (than RAM) ROM devices.

Circuitry is also provided to extend the trailing edge of the write strobes (for both memory and I/O) so that the data buffers remain enabled well beyond the end of the PC Bus write strobes.

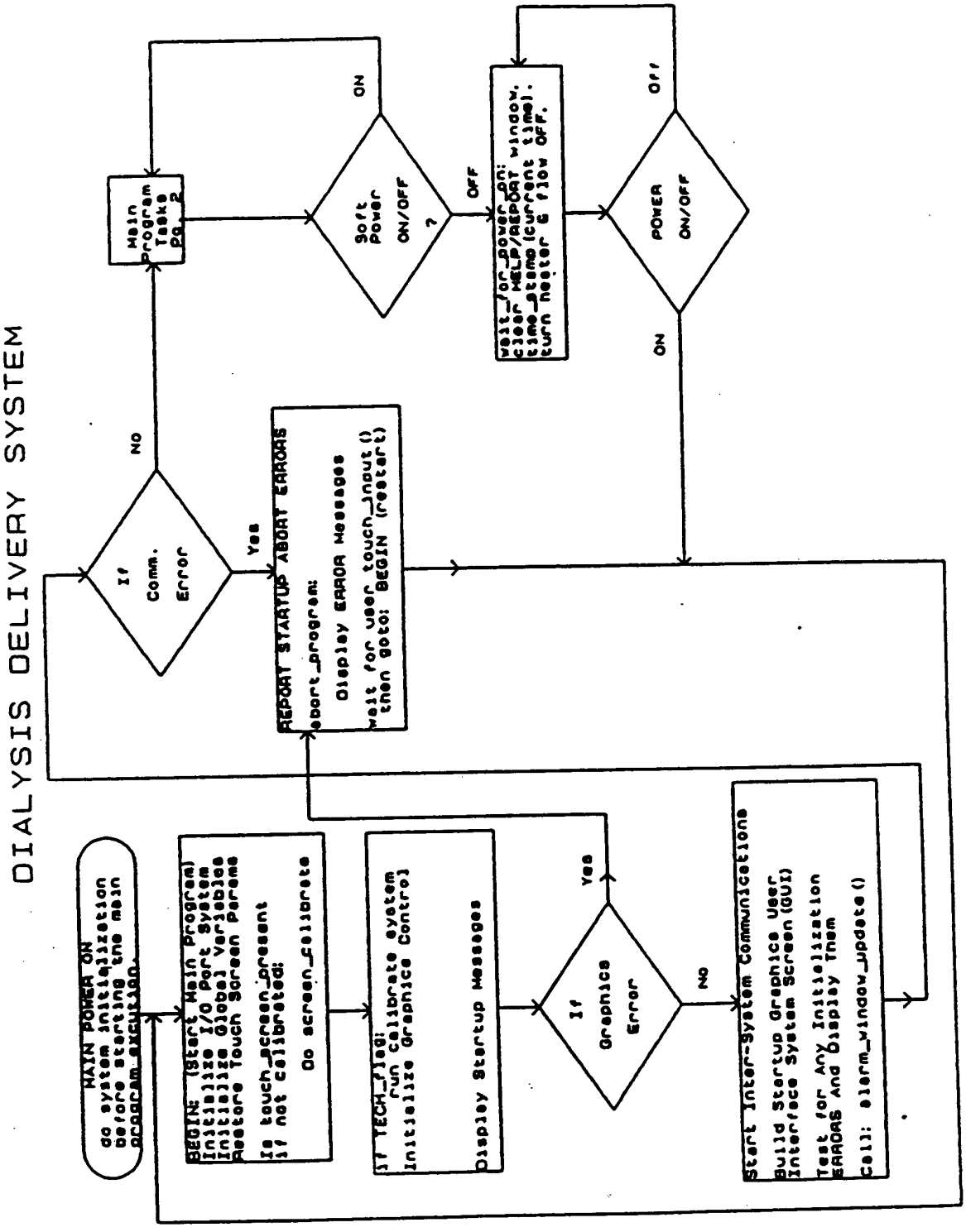
Programmable array logic (PAL) devices are used for address decoding for both memory and I/O devices.

## System Architectur Block Diagram

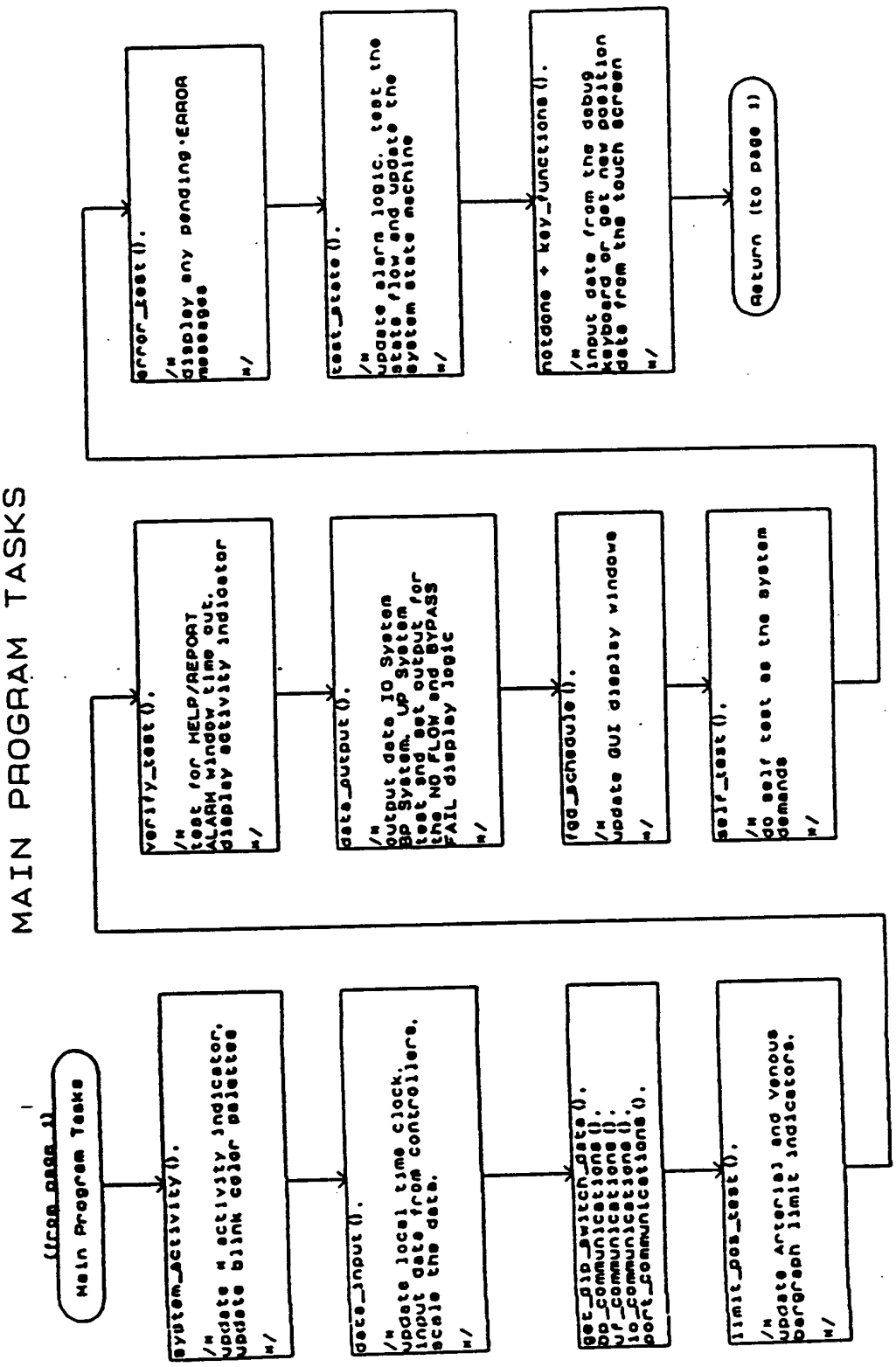



EA 15

## Software Flow Charts

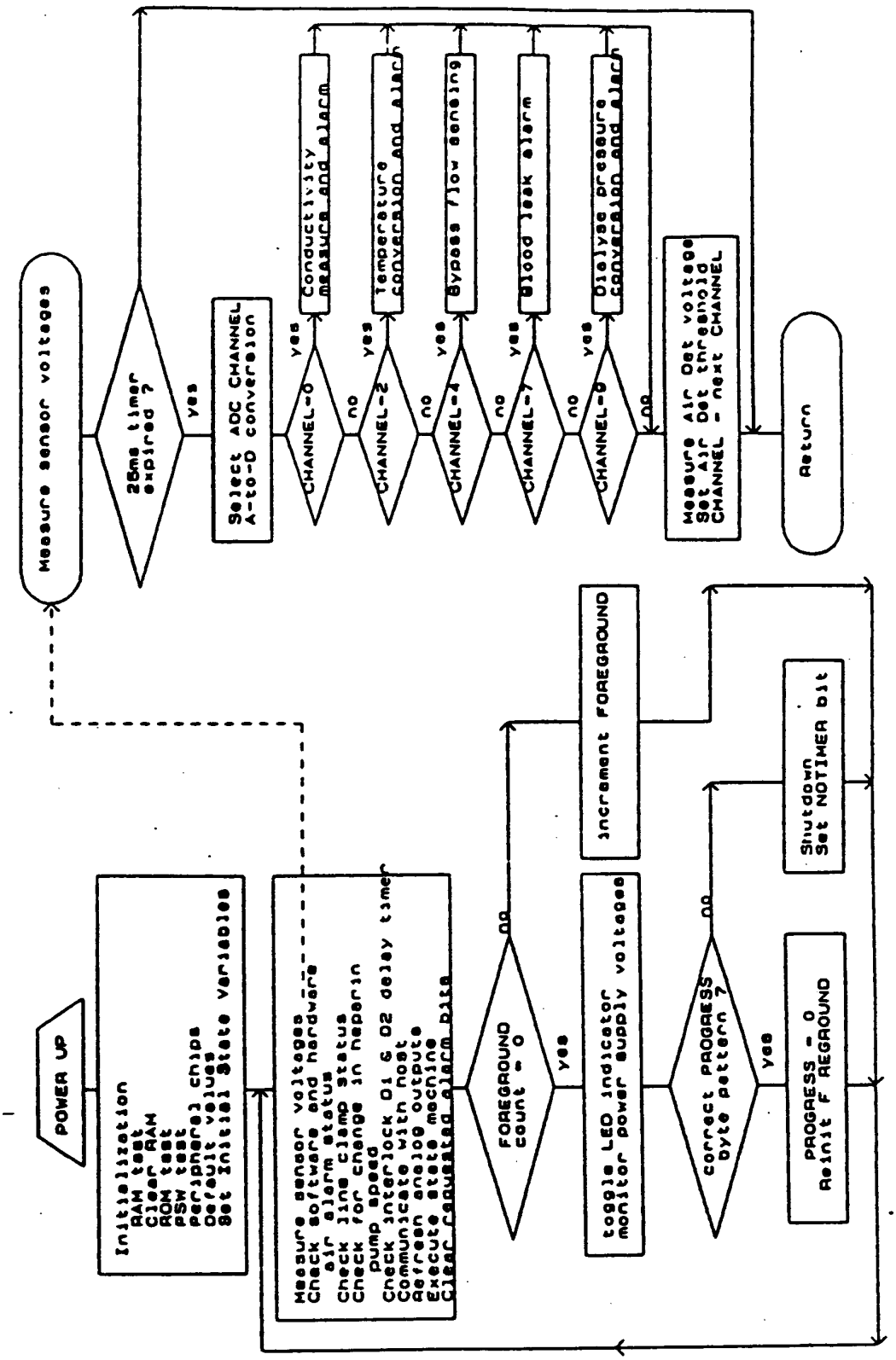



Dialysat Delivery System




Main Program Tasks

I/O Controller Software




I/O Controller Software pag 1

# I/O Controller Software
## *continued*

The circles represent I/O controller states that are charaterized by the following parameters:

Shutdown: Machine in bypass, line clamp clamped, bloopd pump disabled, heparin pump disabled

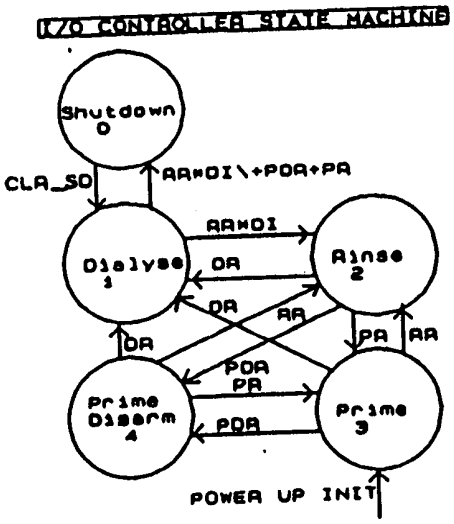
Dialyze: If extracorporeal alarm, controller stops blood pump and clamps line clamp.
If dialysate alarm, controller puts machine in bypass.
If heparin overspeed alarm, controller stops heparin pump.

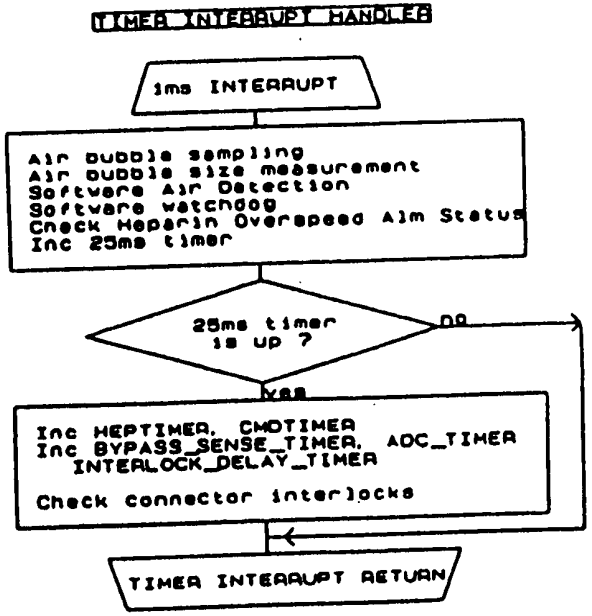
Prime: If extracorporeal alarm, controller stops blood pump and clamps line clamp.
If dialysate alarm, controller puts machine in bypass.
If heparin overspeed alarm, controller stops heparin pump.

Prime Disarm: If dialysate alarm, puts machine in bypass. If extracorporeal alarm (blood leak and air detector only), no controller response.

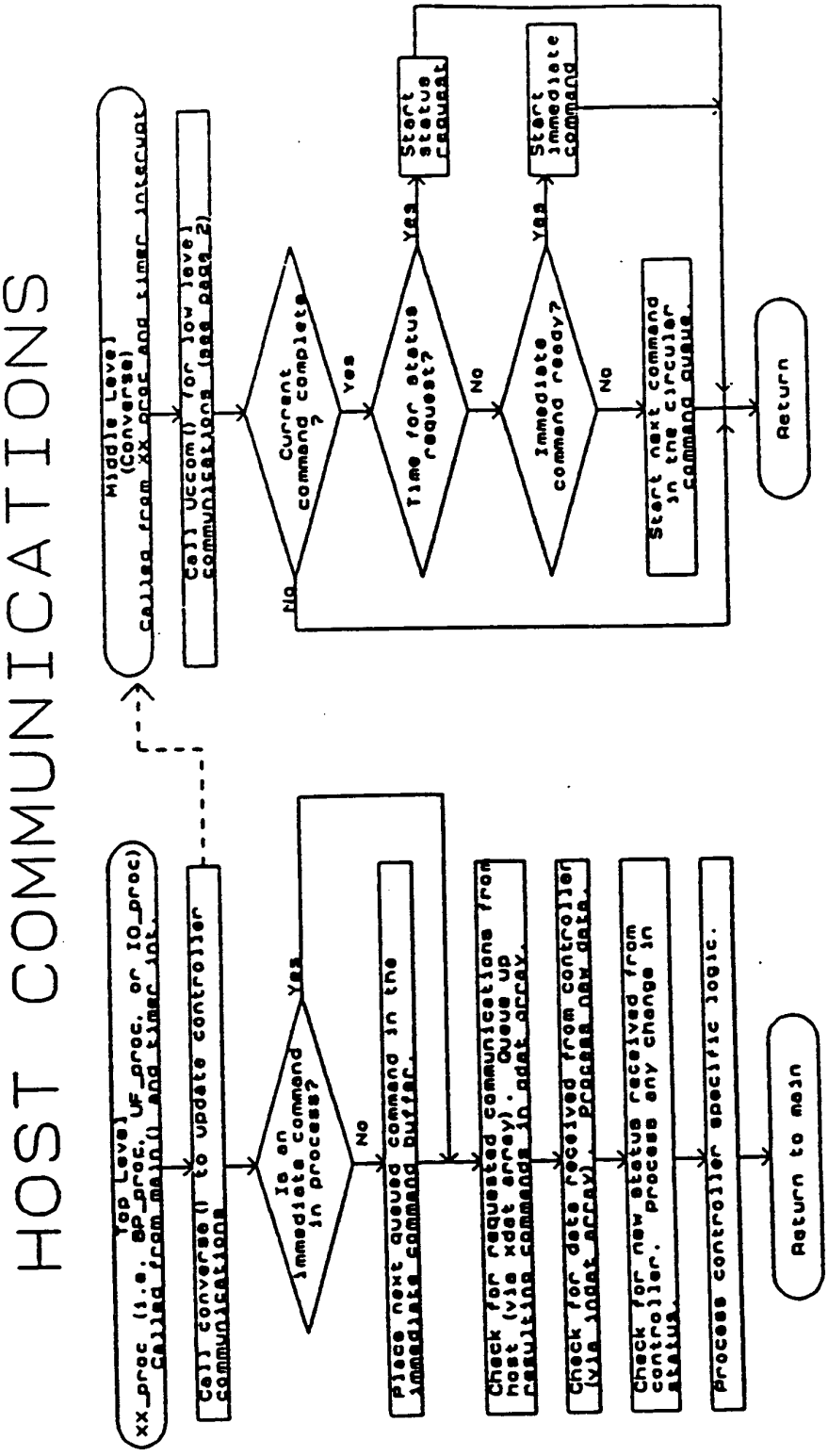
Rinse: Controller does *not* take alarm response actions joutlined in Dialyze state.

The lines denot state transitions with the required signal(s) to make the transition noted beside the lines. These control signals are detailed in the Legend.



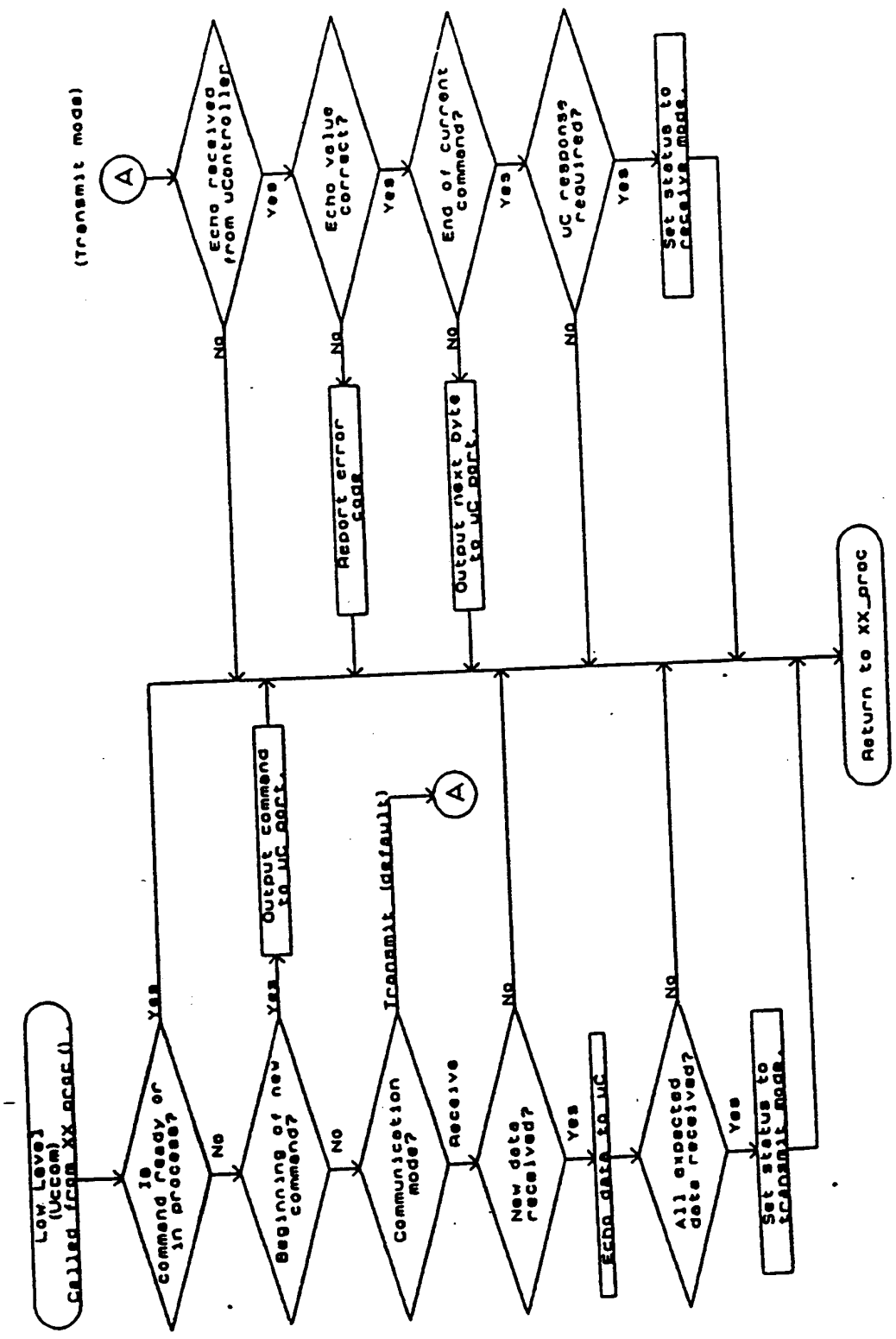



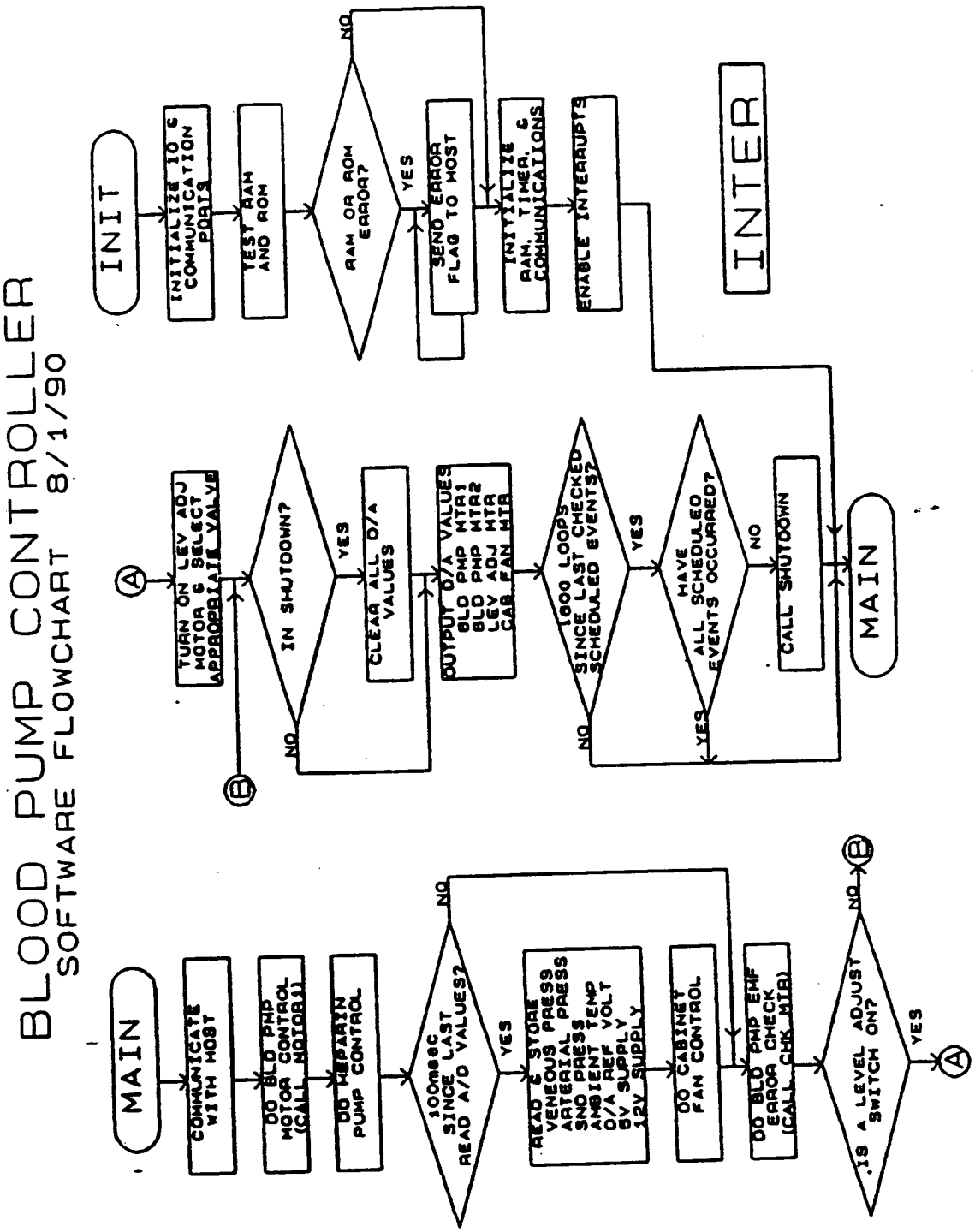

LEGEND:
AR = Rinse Request
DR = Dialyze Request
PR = Prime Request
PDA = Prime Disarm Request
CLR_SD = Clear Shutdown
DI\ = both Dialyzer lines on Rinse fittings




Host Software page 1

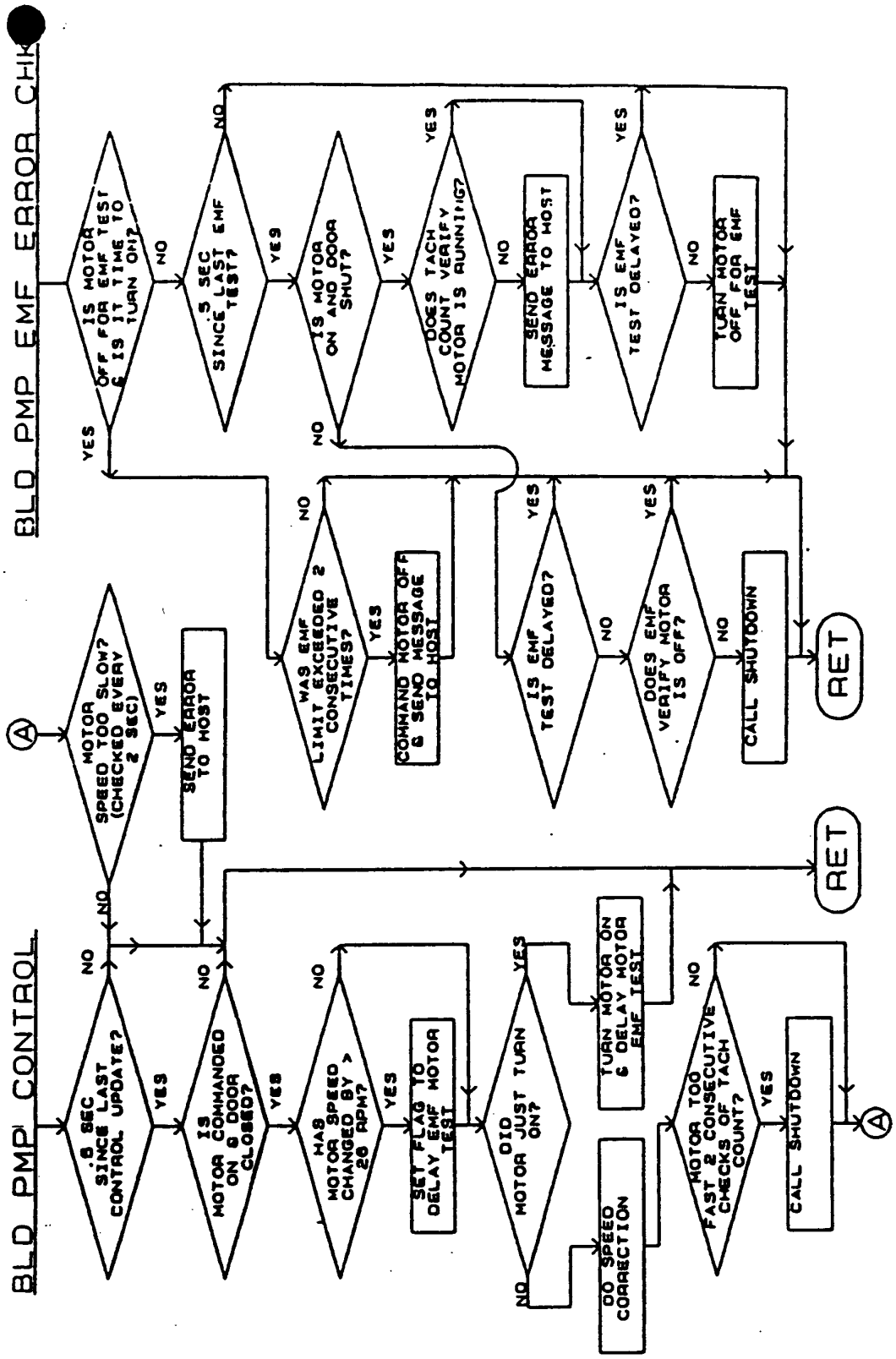
## Host Communications
*continued*





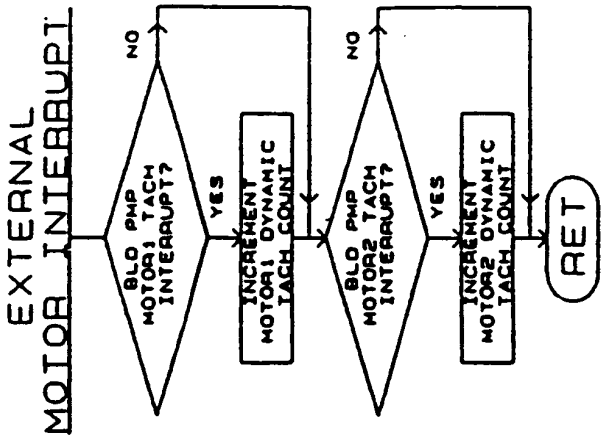

Blood Pump Controller Software page 1

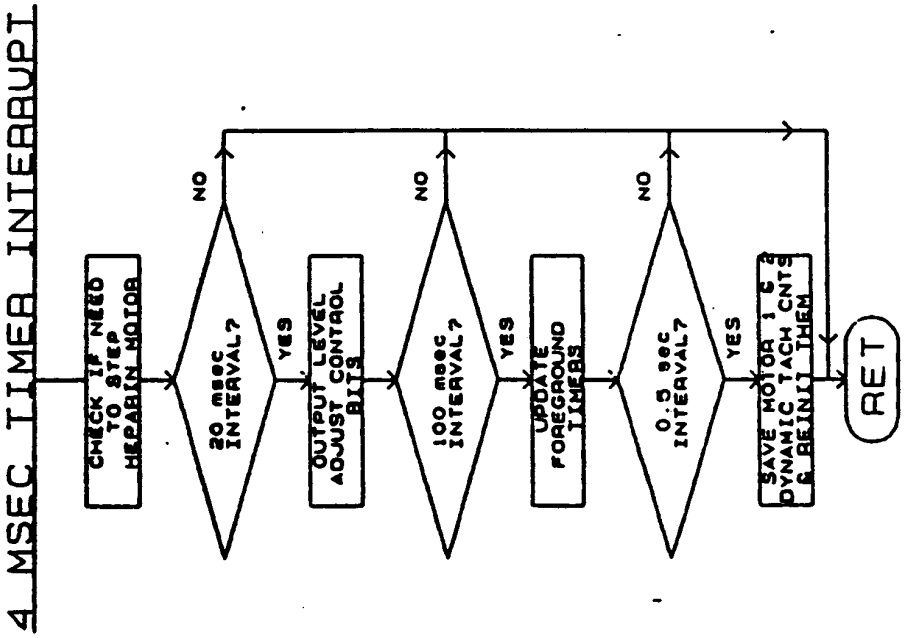
Blood Pump Controller Software
*continued*

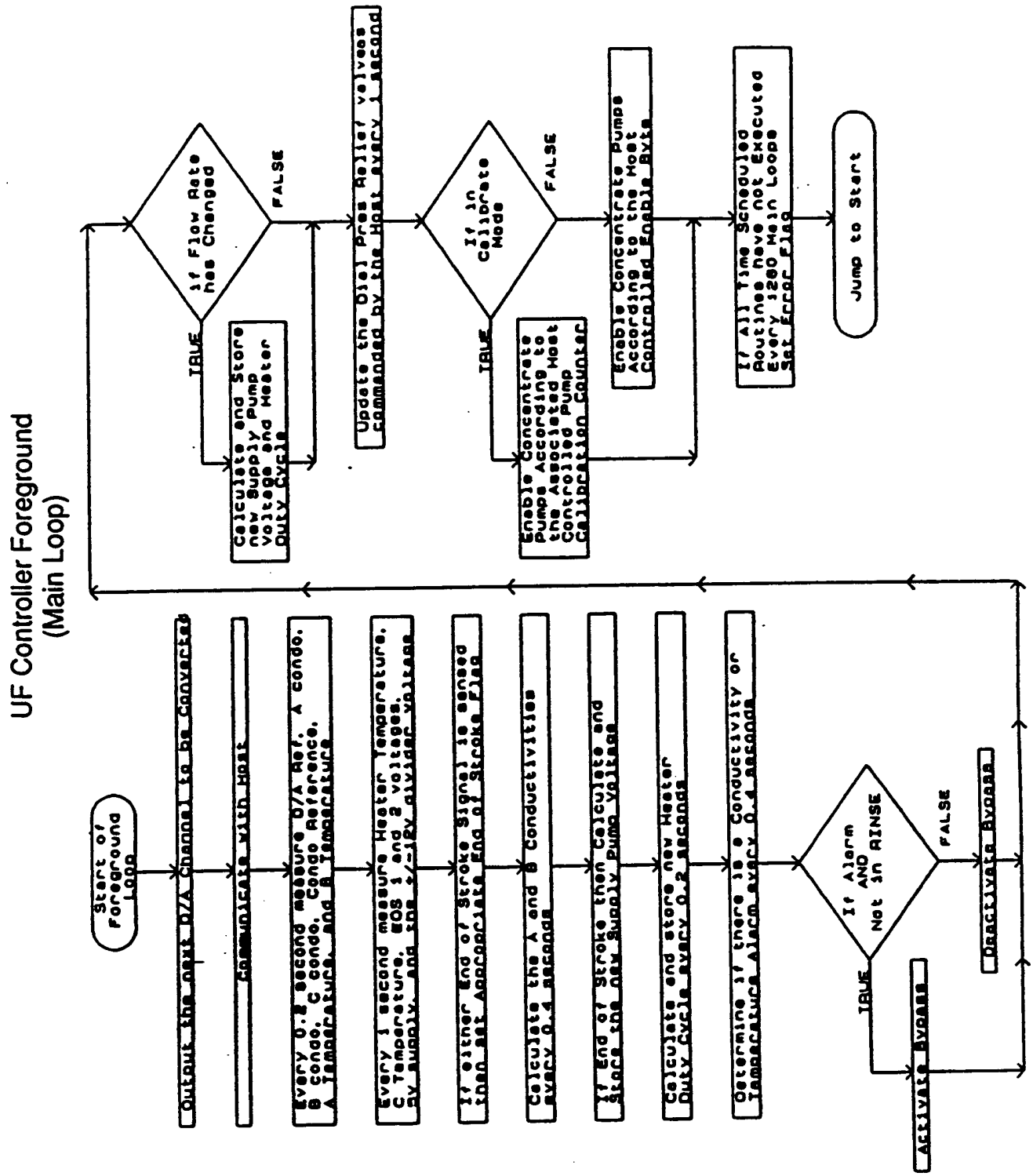



Blood Pump Controller Software page 2

Blood Pump Controller Software
*continued*

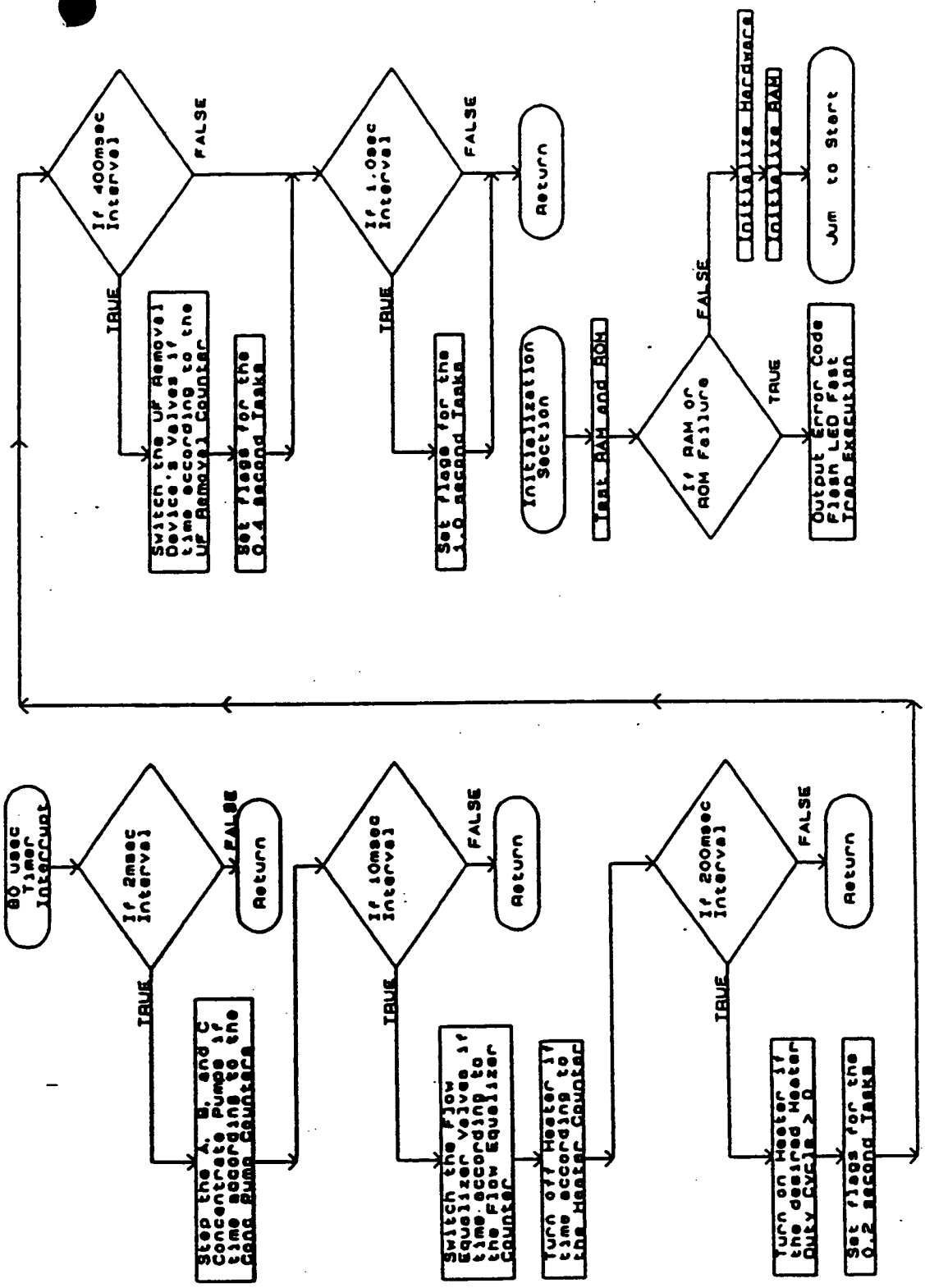




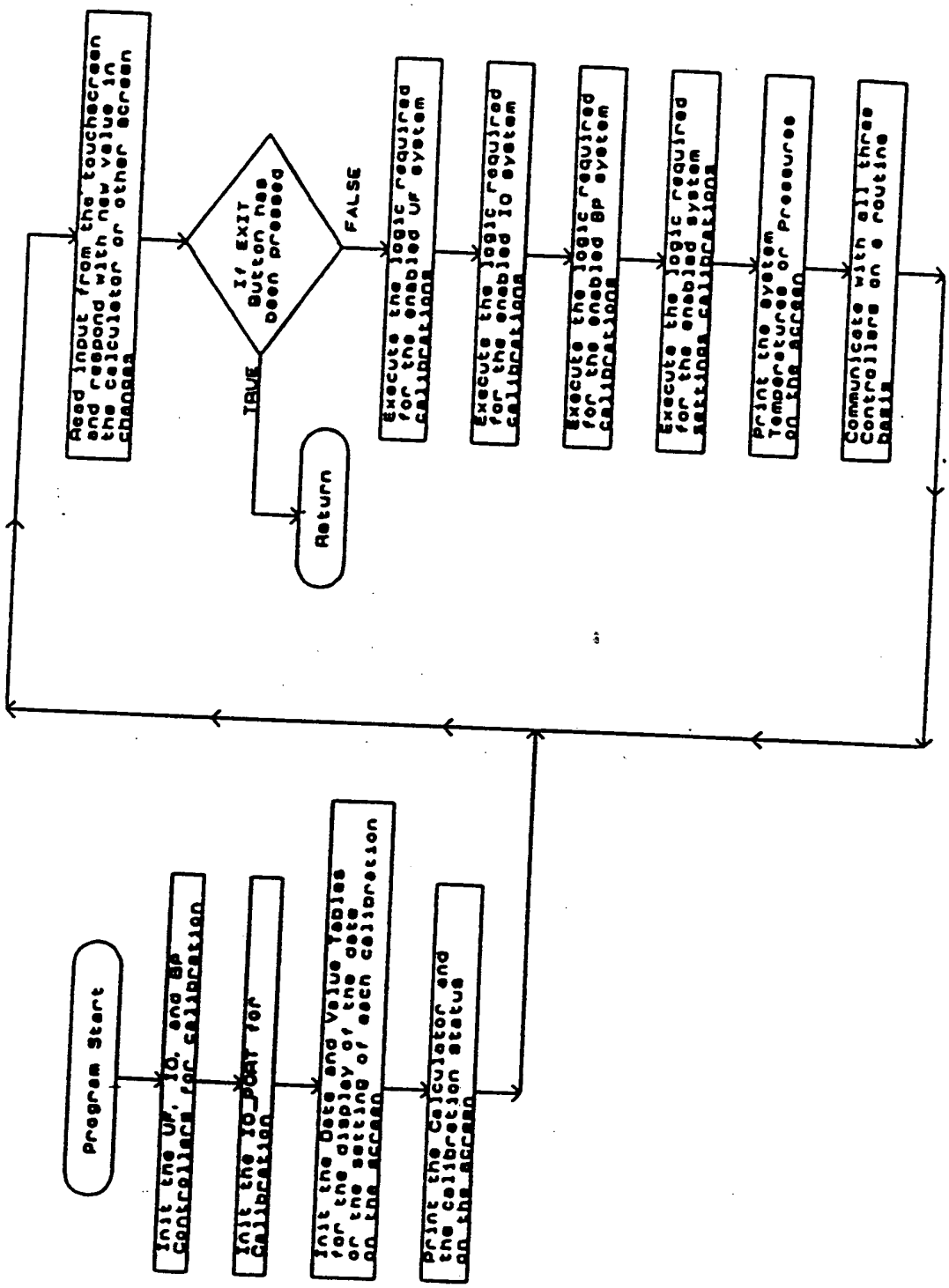

UF Controller Foreground (Main Loop)

UF Controller
(Background and Initialization)




UF Contoller Background and Initialization

Calibration Mode Flow Chart




Calibration Mode Flow Chart